PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference C400.01/I	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 03/02765	International filing date *(day/month/year)* 26.06.2003	Priority date *(day/month/year)* 27.06.2002
International Patent Classification (IPC) or both national classification and IPC G01N33/558		
Applicant INVERNESS MEDICAL SWITZERLAND GMBH et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
24.11.2003	17.08.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Vadot-Van Geldre, E Telephone No. +31 70 340-1973

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/02765

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-18 as originally filed

Claims, Numbers

1-23 as originally filed

Drawings, Sheets

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-9,23 (all partially) and 10-17 .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	11,14,16
	No:	Claims	1-9, 23 (all partially) and 10,12-13,15,17
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-9, 23 (all partially) and 10-17
Industrial applicability (IA)	Yes:	Claims	1-9,23 (all partially) and 10-17
	No:	Claims	

2. Citations and explanations

see separate sheet

1. Reference is made to the following documents:

D1 : EP0421294
D2 : WO9822824
D3 : EP0560411
D4 : US5110550

Re Item IV

Lack of unity of invention

1) This Authority agrees with the ISA that the present inventions lack unity. The reasons are as follows.

1.1. The single general concept which can be identified a priori linking together the claims 1-23 is the following: an assay device comprising liquid transport means characterized in that the "sample presence signal generation means" is not generated by means of an immunoreaction.

1.2. However, D1 (abstract ; column 3, line 54-column 4, line 1 ; column 9, lines 21-26 ; fig 3), D2 (abstract ; claims 1, 12 ; page 8, lines 9-16), D3 (page 4, lines 28-34 ; fig 8) and D4 (column 2, line 40-46 ; column 7, line 10 - column 8, line 11 ; figs 1-2) disclose such assay devices in which a "sample presence signal generation means" is generated non immunologically.

1.3. In the light of D1-D3, each document taken alone, the above identified single general concept is not novel and inventive and can thus not be the single general inventive concept required by Rule 13.1 PCT.

1.4. No other technical features could be identifed that form a technical relationship among each of the separate inventions claimed and which could be considered as special technical features in the sense of Rule 13.2 PCT.

1.5. The application discloses therefore 3 different solutions to a general problem (provision of alternative assay devices).

1.6. Hence the IPEA considers that the following separate inventions or groups of inventions are not so linked as to form a single general inventive concept:

1. Claims 1-9, 23 (all partially) and 10-17 : assay device whereby the "sample presence signal generation means" comprises a coloured portion which is overlaid by a material which when dry is opaque and when wet, becomes sufficiently translucent or transparent to allow the coloured portion to become visible to the user.
2. Claims 1-9, 23 (all partially) and 18-19 : assay device whereby the "sample presence signal generation means" comprises a mobilisable detectable material,

which when wetted by the liquid sample is carried by it resulting in a streaked line.
3. Claims 1-9, 23 (all partially) and 20-22 : assay device whereby the "sample presence signal generation means" comprises a colour changing material immobilised thereon and which undergoes a change in its visible properties upon wetting.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

5.1. The subject-matter of claims 1-9, 23 (all partially), 10,12-13,15,17 does not meet the criteria of Article 33(2) PCT having regard to novelty.

5.1.1. D1 (abstract ; column 3, line 54-column 4, line 1 ; column 9, lines 21-26 ; fig 3), D2 (abstract ; claims 1, 12 ; page 8, lines 9-16), D3 (page 4, lines 28-34 ; fig 8) and D4 (column 2, line 40-46 ; column 7, line 10 - column 8, line 11 ; figs 1-2) all of which disclose chromatographic assay devices comprising a liquid transport means adapted to take up a liquid sample and to conduct the liquid into an "analyte detection region" anticipate the subject-matter of claims 1-9,23.

5.1.2. D4 (column 2, line 40-46 ; column 7, line 10 - column 8, line 11 ; figs 1-2) discloses an assay device wherein the "analyte detection region" is made of a "colour forming layer" which is overlaid with a material which is opaque in dry state and becomes transparent in wet state. The colour forming layer is impregnated with a dye which becomes visible upon sufficiently wetting the different layers of the assay device. Thus, the "analyte detection region" contains a "sample presence signal generation means". Consequently, D4 is also prejudicial to the novelty of claims 10,12-13,15,17.

5.2. The dependent claims do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT (Art. 33(3) PCT) with respect to inventive step, as the relevant subject matter has either been disclosed in prior art (see eg. D2 : discloses the generation of a "control signal" within the analyte detection zone), or falls within the knowledge and ability of the skilled person.

5.3. The claims meet the criteria of Article 33(4) PCT with regard to industrial applicability.

Additional remarks :

Certain published documents (Rule 70.10)

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO03/023371	20-3-2003	10.9.2002	10.9.2001

This earlier application shows chromatographic assay devices wherein the "analyte detection region" is made of a "colored portion" in the form of a minus sign, which is overlaid with a material which is opaque in dry state and becomes transparent in wet state (e.g. nitrocellulose). When no analyte is present a minus sign is visual, when analyte is present a plus sign is formed, because the analyte signal intersects the control signal line (abstract ; par. 30, 33-37, 137-144 ; fig 2-3).